

Bioterrorism Act (BTA) Update - December 2004

On December 6, 2004, FDA released the final rule under the BTA which details the requirements for the Establishment and Maintenance of Records. The rule applies to domestic persons (excluding farms and restaurants) that manufacture, process, pack, transport, distribute, receive, hold or import food, and foreign persons that transport food in the United States. The rule defines a "person" as an individual, partnership, corporation, or association. FDA issued this final rule after reviewing the 212 comments received on the proposed draft of May 9, 2003. For more details, see the FDA press release (which has the relevant web links for this rule) at: <http://www.fda.gov/bbs/topics/news/2004/NEW01143.html>

On November 8, 2004, full enforcement of all data elements in the Registration of Food Facilities and Prior Notice of Imported Food Interim Final Rules under the BTA began. The U.S. Food and Drug Administration (FDA) and the U.S. Customs and Border Protection (CBP) issued both rules on October 10, 2003. Those rules took effect as required by the BTA on December 12, 2003; however, FDA and CBP have been exercising enforcement discretion since December 2003, with a gradual phase-in of enforcement of the various data elements. Full enforcement entails refusal and/or assessment of civil monetary penalties when prior notice submissions are inadequate.

FDA also has issued a revised compliance guide (CPG) that affords additional enforcement discretion for prior notice submissions that do not provide information about the identity of the manufacturing facility of food no longer in its natural state, articles of food imported or offered for import by express courier, prior notice submission time frames, and gift packs purchased or otherwise acquired by an individual and imported or offered for import for nonbusiness purposes. Copies of the rules, fact sheets, and the CPG is available at: <http://www.cfsan.fda.gov/~dms/fsbtact.html>

As of December 8, approximately 234,000 food facilities have registered with FDA as required under the Bioterrorism Act. Approximately 128,000 are foreign facilities and 106,000 are U.S. facilities.

Extensive information about the Bioterrorism Act is available on the FDA's website at: <http://www.fda.gov/oc/bioterrorism/bioact.html>